

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

CELSIS IN VITRO, INC.  
a Maryland Corporation,

*Plaintiff,*

v.

Case No. \_\_\_\_\_

CELLZDIRECT, INC., a Delaware Corporation  
and wholly-owned subsidiary of INVITROGEN  
CORPORATION; and INVITROGEN  
CORPORATION, a Delaware Corporation.

*Defendants.*

**DECLARATION OF MARK A. PETERSON**  
**REDACTED VERSION**

**Declaration of Mark A. Peterson**

I, Mark A. Peterson, hereby declare as follows:

1. At the request of Loeb & Loeb LLP (Loeb & Loeb), counsel to Celsis In Vitro, Inc. (Celsis IVT), I have been asked to opine on issues regarding irreparable harm to Celsis IVT as a result of the alleged infringement of U.S. Patent No. 7,604,929 (the '929 Patent) by CellzDirect, Inc. (CellzDirect) and Invitrogen Corporation (Invitrogen) (herein, collectively referred to as CellzDirect). Loeb & Loeb asked me to analyze certain information and form an opinion on irreparable harm, if any, as a result of CellzDirect's alleged infringement of the '929 Patent. In the course of this assignment, I was asked to rely on sales information produced by Celsis IVT, as well as representations from Judy Madden, Vice President of Strategic Development for Celsis International Ltd. (Celsis), and Daniel Dryden, Director of Product Operations for Celsis IVT.
2. I am the founder of Robinwood Consulting LLC (Robinwood Consulting), a firm focused primarily on the valuation of intellectual property and the calculation of economic damages in litigation. For approximately 23 years, I have spent the majority of my time valuing intellectual property in licensing and litigation matters. I have addressed such issues as lost profits, reasonable royalties, price erosion, convoyed sales, and market share, as well as other business

and economic considerations in both litigation and licensing matters. I have been admitted as a damages expert in Federal and State Courts approximately 15 times. I have also testified as an expert at the International Trade Commission on the issue of irreparable harm. My resume is included as Exhibit 1 to my declaration.

**Irreparable Harm To Celsis IVT**

3. I understand that Celsis IVT alleges it has and continues to suffer irreparable harm as long as CellzDirect continues to sell products allegedly infringing the '929 Patent (accused products). Celsis IVT alleges it suffers from loss of revenue due to price erosion, loss of goodwill attributable to a market leader in a growth market, and loss of additional business opportunities. Furthermore, Celsis IVT alleges its leadership position in the human cryopreserved hepatocytes (liver cell) market and potentially other markets has and continues to be impaired as a result of (1) sales of CellzDirect's accused products, and (2) any misrepresentations, if any, to market participants (i.e., current and potential customers) at conferences and workshops.
4. I understand that in order to support a finding of irreparable harm, the patentee is required to offer evidence that the harm is not totally compensable, and that measurable monetary damages will not fully make the patentee whole. In this matter, some harm (i.e., short term

harm) may be known, compensable, and able to be measured with a reasonable degree of certainty, such as specific lost sales to a customer as result of the alleged infringement.

5. While some of the short term harm may be measurable, much of the real harm is not. There are several reasons why much of the harm is difficult (or nearly impossible) to measure. For instance, it is my understanding that leadership position, reputation and goodwill with customers and other market participants are extremely important factors in order to effectively market and sell hepatocyte products. If leadership position, reputation and goodwill are negatively impacted as a result of alleged patent infringement, then there are relatively immeasurable negative "ripple" (less direct) effects to the patentee.
6. Below, I will demonstrate and explain in some detail that Celsis IVT has lowered its prices on its patented LiverPool™ products in order to maintain market share and customer relations, and that this price erosion is likely to continue unless, as alleged by Celsis IVT, CellzDirect ceases to sell accused products. And, it is highly unlikely that Celsis IVT will be able to raise its prices back to where it would have been prior to the sale of CellzDirect's accused products (another reason supporting the difficulty in measuring harm).



Some Relevant Information Regarding Celsis IVT

7. Beginning in 2005, Celsis IVT began selling its patented LiverPool products to pharmaceutical and biotechnology firms worldwide. These types of LiverPool products include: 5-, 10-, 20-, and 50- Donor Pooled Cryopreserved Human hepatocytes.<sup>1</sup>
8. According to Ms. Madden, the LiverPool products are still in their growth phase of the product life cycle. This phase is generally the time period when a company distinguishes itself from competitors, expands its customer base, and establishes its reputation and leadership position. If Celsis IVT is denied certain leadership opportunities due to the alleged infringement of the '929 Patent, then Celsis IVT will be irreparably harmed in a manner that is very difficult to measure for estimating damages particularly in light of my discussion below.
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<sup>1</sup> Celsis IVT's 10-Donor product is available as a mixed gender pool, female pool, or male pool.

<sup>2</sup> Exhibit 2, SUM-100.

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10. Celsis IVT filed a patent application on April 21, 2005, and was granted U.S. Patent No. 7,604,929 B2 (the '929 Patent) on October 20, 2009, entitled "Cellular Compositions And Methods For Their Preparation." I understand the '929 Patent provides for, but is not limited to, the following:

- Ease of use due to Celsis IVT's ability to provide multiple donor cryopreserved pooled lots;
- Convenience due to the elimination of the need to pool individual vials of cells;
- Cost savings to users due to a decrease in the number of vials purchased with pre-pooled product; and,
- Lower variability observed from study-to-study allowing for time and cost savings.

11. According to Ms. Madden and Mr. Dryden, the process to make the LiverPool products is protected by the '929 Patent. REDACTED

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According to Ms. Madden, I understand the following regarding LiverPool products and the hepatocyte market:

- 1) LiverPool products demand a significant pricing advantage  
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(unpatented) hepatocyte products in the marketplace;
- 2) There are very little, if any, price discounts for proprietary  
(patented) products in this market.  
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- 3) The market for human cryopreserved hepatocytes products is price  
sensitive for many pharmaceutical customers. Purchasing  
departments at pharmaceutical companies are attentive to prices  
for hepatocyte products used for its R&D efforts.

**Some Relevant Information Regarding CellzDirect**

12. According to its website, CellzDirect sells and markets cryopreserved hepatocytes for pharmaceutical and biotechnology companies worldwide.<sup>3</sup> According to Ms. Madden, I understand that CellzDirect's accused products and related services are in direct competition to Celsis IVT's LiverPool products and services.
13. In September 2006, CellzDirect and Advanced Pharmaceutical Sciences, Inc. (APS) entered into a five year exclusive agreement.<sup>4</sup> I understand this agreement allowed APS to exclusively produce cryopreserved human hepatocytes for CellzDirect. According to CellzDirect's press

<sup>3</sup> [www.cellzdirect.com/3.3-CryopreservedHepatocytes.htm](http://www.cellzdirect.com/3.3-CryopreservedHepatocytes.htm).

<sup>4</sup> [www.cellzdirect.com/n\\_2006\\_09\\_14.htm](http://www.cellzdirect.com/n_2006_09_14.htm).

release, APS is headed by President and CEO Dr. Albert P. Li, a leading researcher and pioneer in hepatocyte isolation and cryopreservation.<sup>5</sup>

14. I also understand that on January 10, 2008, Invitrogen announced its purchase of CellzDirect for approximately \$57 million.<sup>6</sup> According to CellzDirect's press release, one of the reasons for Invitrogen's purchase of CellzDirect was its *leadership position in a high-growth hepatocyte market*.

15. If Celsis IVT's patented technology has and continues to contribute to CellzDirect's market position (instead of exclusively contributing to the market position of Celsis IVT), then CellzDirect's leadership position and marketing practices have and continue to have a negative impact on Celsis IVT's efforts to market and sell its products and Celsis IVT's reputation with customers and other market participants.

#### **Some Evidence Of Price Erosion**

16. Since CellzDirect began marketing and selling its accused products, I understand that Celsis IVT has been forced to lower prices for its LiverPool products for two primary reasons: (1) to match or beat CellzDirect's accused product prices with current customers, and (2) to

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<sup>5</sup> According to Ms. Madden, Dr. Li is the former Chief Scientific Officer of In Vitro Technologies, Inc., the predecessor company of Celsis IVT.

<sup>6</sup> [www.cellzdirect.com/2.3-news.htm](http://www.cellzdirect.com/2.3-news.htm).



remain competitive with CellzDirect's accused product prices for potential new customers.

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<sup>7</sup> Exhibit 2, SUM-115.

<sup>8</sup> Exhibit 2, SUM-125.

<sup>9</sup> Exhibit 2, SUM-230.

<sup>10</sup> Exhibit 2, SUM-210.

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21. According to Ms. Madden, I understand a Celsis IVT customer REDACTED REDACTED left for CellzDirect, only to return to Celsis IVT. This customer was not satisfied with CellzDirect's accused products, and considered LiverPool to be higher quality and more reliable. According to Ms. Madden, this customer eventually returned to purchasing LiverPool, but only after Celsis IVT reluctantly met this customer's price demands. Thus, despite a higher quality product, Celsis IVT has lost its pricing advantage with this customer as well as substantial sales. The above example supports the following concepts:

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<sup>11</sup> Exhibit 2, SUM-260.

<sup>12</sup> Exhibit 2, SUM-240.

- 1) Celsis IVT has asserted that LiverPool products are superior to that of CellzDirect's accused products. If so, CellzDirect's inferior products are hurting the market, as some customers become accustomed to a lower quality, lower priced product; something that is likely irreversible.
- 2) CellzDirect's market presence has caused potentially irreversible price erosion. Celsis IVT's pricing advantage has largely faded with several important customers. This harm associated with Celsis IVT's irreversible price advantage is something that is very difficult to measure.
- 3) While some customers could return to Celsis IVT after leaving for an inferior product, some customers will never return, and we may not know the reasons why. Because customer preferences vary due to pricing and quality factors, it is very difficult (or mostly impossible) to measure those lost sales (i.e., both historical and future lost sales).

22. According to Ms. Madden, LiverPool's price erosion is primarily attributable to CellzDirect's pricing of its accused products, as opposed to some other factors (i.e., recessionary reasons). At this time, I have not been able to identify a benchmark on pricing levels associated with research and development costs for pharmaceutical and biotechnology

firms in order to compare it to Celsis IVT's price erosion during the relevant period.<sup>13</sup> This only supports the level of difficulty associated with measuring the amount of price erosion due to CellzDirect versus other factors.

#### **Nature Of Industry And Multiple Facets Of Harm**

23. According to Ms. Madden, I understand there are a small number of companies that supply hepatocyte products to pharmaceutical and biotechnology companies. Companies' reputations are created by the quality of products and services offered and innovative contributions in the field of drug development. According to Ms. Madden, the alleged infringement is creating a more difficult atmosphere in which Celsis IVT advertises its products and promotes its leadership position in the market.

24. For example, at regional, national, and international conferences and workshops, Celsis IVT does not know all of the representations made by CellzDirect regarding its products and LiverPool. Thus, according to Ms. Madden, Celsis IVT may be harmed as a result of misrepresentations, if any, made in the market. This harm is also very

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<sup>13</sup> During my preliminary investigation of a benchmark index, I was able to identify the Biomedical Research and Development Price Index (BRDPI) issued by the U.S. Department Of Health & Human Services. The BRDPI measures changes of prices for inputs (e.g., personnel services, supplies, equipment, etc.) purchased with the National Institutes of Health (NIH) budget to support research. For reference purposes only, the annual increase for the BRDPI ranged from 3.4% - 4.7% for years 2006-2009.



difficult to measure, as it can have negative ripple effects (i.e., lost sales opportunities for LiverPool as well as other non-patented products and services).

25. According to Ms. Madden, Celsis IVT seeks (a) to represent to market participants that it is the only firm marketing and selling pre-pooled cryopreserved hepatocyte products, and (b) provide its ideas and research to current and potential customers. At this time, Celsis IVT cannot prevent CellzDirect from promoting its accused products without a Court Order. The value of the exclusive leadership position is not easy to define and measure because there are a lot of unknowns (i.e., loss of revenue due to loss of leadership position, loss of revenue due to unknown factors which drive customers' purchasing decisions, etc.). As a result, Celsis IVT has and continues to potentially lose both current and new customers and business opportunities. And furthermore, impairment to reputation and goodwill may lead to losses of other Celsis IVT products and services.

26. According to Ms. Madden, each customer is a unique opportunity, and customers have different purchasing preferences (i.e., utility, quality, price, reputation, etc.). Some customers are willing to spend more money for LiverPool, while other customers are not necessarily willing to spend more money for higher quality product. Reality is that many

factors affect product prices, and thus, it is not easy to prove that a decline in market price is entirely attributable to CellzDirect's sales of accused products. Therefore, there are significant challenges when measuring the real historical price erosion and lost sales during the period from when CellzDirect began selling the accused products to the present, as well as future price erosion and lost sales.

27. According to Ms. Madden, I understand that some customers buy their research products only once or twice every year. This concept is supported by Celsis IVT's sales to REDACTED from 2006 to present.<sup>14</sup> If Celsis IVT misses the opportunity to sell its products, then Celsis IVT is most likely not going to sell products for several months, if ever, because the customer may become accustomed to another supplier's products and services.

28. According to Ms. Madden, I understand that, in addition to hepatocyte products, customers in the general market at issue often purchase non-patented products and services at the same time from the same supplier. Celsis IVT's market leadership position is potentially being eroded for non-patented products and services as well. Therefore, not only is Celsis IVT alleging lost market opportunities of its LiverPool products from the alleged infringement of the '929 Patent, but also

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<sup>14</sup> Exhibit 2, SUM-270 and SUM-280.

losing sales of non-patented products and services, which also may be very difficult to measure or to be adequately compensated.

### Conclusions

29. I have analyzed LiverPool sales information by product and by customer. At this time, I have concluded that Celsis IVT's average prices began to decline at or about the same time CellzDirect began marketing and selling of its accused products. Additionally, this price erosion is more than likely to be irreversible, and very difficult to measure. This price erosion will continue to harm Celsis IVT unless the accused products are removed from the market.

30. Celsis IVT alleges its goodwill and reputation as a market leader within the hypatocyte market has been and continues to be impaired as a result of the alleged infringement. This loss is also very difficult to measure or adequately compensated. Based on my understanding, the remedies available are inadequate or unlikely to compensate Celsis IVT for the alleged infringement by CellzDirect of the '929 Patent.

31. If CellzDirect continues to sell the accused products, there is a strong likelihood of future losses due to additional lost business opportunities for non-patented products and services that will be very difficult to measure if Celsis IVT's motion for preliminary injunction is denied.

Celsis IVT will likely be irreversibly harmed if customers are allowed to continue to choose to purchase CellzDirect's lower quality and lower priced accused infringing products.

I declare under penalty of perjury that the foregoing is true and correct.  
Executed this 22<sup>nd</sup> day of June 2010 in Chicago, Illinois.



Mark A. Peterson

**Mark A.  
Peterson**

Digitally signed by Mark A.  
Peterson  
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